## REMARKS

This amendment is responsive to the Office Action dated June 24, 2005. Applicant has amended claims 1 and 7, cancelled claims 2 and 16, and added new claims 24 and 25. Claims 1, 3-15 and 17-25 are pending.

### Objection to the Drawings

In the Office Action, the Examiner objected to the drawings because they included reference characters (403A and 403B) not mentioned in the specification. Applicant has amended paragraph **[0044]** of the specification to correct a typographical error that resulted in the omission of the reference characters from the specification. Accordingly, as amended, the specification now mentions the reference characters. Applicant respectfully requests withdrawal of the objection to the drawings.

### Rejection for Obviousness-type Double Patenting

The Examiner provisionally rejected claims 1 and 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/731,638.

Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied, i.e., when the application no. 10/731,638 is granted.

### Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 3, 7, 8, 11, 12 and 14-23 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,399,820 to Wirtzfeld et al. (Wirtzfeld). Applicant respectfully traverses these rejections, to the extent such rejections may be considered applicable to the amended claims. Wirtzfeld fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and neither Wirtzfeld, nor the other applied references, provides any teaching that would have suggested the desirability of modification to include such features.

*Claims 1 and 3*

For example, Wirtzfeld fails to teach or suggest an overmold that at least partially encapsulates each of at least two housings and a coupling module that is coupled to each of the housings, as recited by Applicant's independent claim 1 as amended. In the Office Action, the Examiner acknowledged that Wirtzfeld fails to teach or suggest this requirement of amended claim 1.[1] Accordingly, it appears that Applicant and the Examiner agree that rejection of amended claim 1 under section 102 would be improper, and that the rejection of claims 1 and 3 under section 102 should be withdrawn.

This requirement was originally recited in claim 2, now cancelled, which the Examiner rejected under section 103 as obvious over Wirtzfeld in view of U.S. Patent No. 6,176,879 to Reischl et al. (Reischl). The Examiner argued that Reischl discloses modules encased in biocompatible housings, and that "[i]t would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with the biocompatible housing material of Reischl for the purpose of sealing the modules against contamination and holding the modules in a fixed position relative to one another."[2] Applicant respectfully disagrees with the Examiner's characterization of Reischl, and the conclusion that the requirements of amended claim 1 would have been obvious over Wirtzfeld in view of Reischl.

First, contrary to the Examiner's argument, Reischl does not disclose a plurality of housings, or an overmold that at least partially encapsulates a plurality of housings. Instead, Reischl discloses a device comprising a single housing, with various components therein. The single housing disclosed by Reischl is not an overmold within the meaning of amended claim 1, because it does not at least partially encapsulate each of a plurality of housings, as recited in amended claim 1. Further, Reischl does not even suggest that the single housing disclosed therein is encapsulated by an overmold, much less a device comprising a plurality of such housings, each encapsulated by an overmold, as required by amended claim 1.

In sum, like Wirtzfeld, Reischl fails to teach or suggest an overmold that at least partially encapsulates each of at least two housings and a coupling module that is coupled to each of the housings, as required by amended claim 1. In other words, even when combined as suggested by

[1] Office Action, page 4.
[2] *Id.* at page 5.

the Examiner, Wirtzfeld and Reischl still fail to teach the requirements of amended claim 1. Neither Wirtzfeld, nor Reischl, nor any of the other cited references teaches or suggests an overmold that at least partially encapsulates each of at least two housings and a coupling module that is coupled to each of the housings, as required by amended independent claim 1.

Further, one of ordinary skill in the art would not have been motivated to modify the Wirtzfeld device per Reischl as suggested by the Examiner, nor had a reasonable expectation that such a combination would be successful. Wirtzfeld discloses a heart pacemaker coupled to a flexible, intravenously implanted cardiac catheter or lead.[3] The catheter includes a measurement probe at its distal end, which is located within a chamber of the heart. The Examiner argued that the pacemaker and probe meet the requirement in amended claim 1 of two modules with respective housings, and that the catheter meets the requirement in amended claim 1 of a coupling module coupled to each of the modules.[4] Further, as discussed above, the Examiner argued that "[i]t would have been obvious to one of ordinary skill in the art to combine the teachings of Wirtzfeld with the biocompatible housing material of Reischl for the purpose of sealing the modules against contamination and holding the modules in a fixed position relative to one another."[5]

In other words, the Examiner appears to argue that it would have been obvious to one of ordinary skill to use the housing materials described by Reischl to form an overmold that at least partially encapsulates each of the pacemaker, catheter and module described by Wirtzfeld. However, as discussed above, there is no suggestion in any of the applied references of an overmold. Further, there is no teaching in any of the applied references, and particularly Reischl, that would have suggested use of the housing materials described by Reischl to encapsulate the spatially distributed components described by Wirtzfeld in the manner suggested by the Examiner. Moreover, use of the housing materials described by Reischl to encapsulate the components described by Wirtzfeld in the manner suggested by the Examiner would completely frustrate the intended uses and advantages of the device described by Wirtzfeld.

Wirtzfeld states following with respect to the key advantages achieved by the invention described therein:

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[3] Wirtzfeld: Abstract; column 3, lines 1-23; column 4, lines 7-17; FIG. 1.
[4] Office Action, page 3.
[5] *Id.* at page 5.

> The catheter with the measuring probe according to the invention is virtually identical in its mechanical construction with the bipolar catheters which have long been in use, and accordingly entails no additional problems with respect to the long-term mechanical strength and implantation technique....[6]

At least partially encapsulating each of the pacemaker, catheter and module described by Wirtzfeld with the housing materials described by Reischl, as suggested by the Examiner, would entirely eliminate these advantages. The housing materials described by Wirtzfeld are rigid materials, such as titanium and ceramic. The Examiner acknowledged this, arguing that a reason that one of ordinary skill in the art would have been motivated to combine the Wirtzfeld and Reischl teachings would be to "[hold] the modules in a fixed position relative to one another."[7]

One of ordinary skill in the art would not have been motivated to modify Wirtzfeld device in any manner that would have resulted in the pacemaker and sensor module being held in a fixed position relative to teach other, much less the manner suggested by the Examiner. On the contrary, the catheter described by Wirtzfield must be generally flexible and movable relative to the pacemaker to permit travel through the heart. One of ordinary skill would have recognized that at least partially encapsulating the pacemaker, catheter and module described by Wirtzfeld within the rigid housing materials described by Reischl would lead to significant problems with respect to their implantation, and particularly intravenous implantation of the catheter, entirely frustrating the intended uses and advantages of the Wirtzfeld device. For this reason, one of ordinary skill in the art would not have been motivated to make the modification suggested by the Examiner to the Wirtzfeld device, or reasonably believed that such a modification would be successful. Indeed, one of ordinary skill in the art would have consciously avoided such a modification of the Wirtzfeld device in order to ensure operability of the Wirtzfeld device for its intended purpose.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1 and 3 under 35 U.S.C. §§ 102(b) or 103(a). Withdrawal of the rejections of these claims is requested.

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[6] Wirtzfeld: column 3, lines 14-21 (emphasis added).
[7] Office Action, page 5.

*Claims 7, 8, 11, 12 and 14-23*

As amended, independent claim 7 requires a coupling module that is fixedly coupled to first and second housings, and is made of a metal that defines a lumen between the first and second housings. Wirtzfeld fails to teach or suggest this requirement of amended claim 7.

In rejecting claim 7 as previously presented, the Examiner argued that the pacemaker and sensor probe described by Wirtzfeld anticipates the requirement of two modules with respective housings, and that the catheter described by Wirtzfeld anticipates the requirement of a coupling module fixedly coupled to each of the housings.[8] However, Wirtzfeld does not teach or suggest that the catheter is made of metal, as required by amended claim 7.

Dependent claim 16 as previously presented, now cancelled in view of the amendment to independent claim 7, required that the coupling module be made of metal. In rejecting claim 16 under section 102 over Wirtzfeld, the Examiner evidently recognized that Wirtzfeld does not teach or suggest that the catheter is made of metal. The Examiner instead argued that metallic annular elements 31 and 34 described by Wirtzfeld anticipate the requirement of a coupling module made of metal.

The Examiner's rejections of claims 7 and 16 as previously presented are confusing and unclear. In particular, it is unclear whether the Examiner is arguing that metallic annular elements themselves meet the requirement of a coupling module that is made of metal, or that the catheter and metallic annular elements together meet the requirement of a coupling module that is made of metal. In any event, both arguments are incorrect, particularly in view of the requirements of amended claim 7 with respect to the recited coupling module.

The metallic annular elements described by Wirtzfeld clearly do not themselves meet the requirements of amended claim 7 with respect to the recited coupling module. For example, the metallic annular elements are not fixedly coupled to first and second housings of first and second modules, as required by amended claim 7. As clearly depicted in FIGS. 2-5 of Wirtzfeld, the metallic annular elements are internal components of the sensor module described by Wirtzfeld, and are not in any way fixedly coupled to the pacemaker described by Wirtzfeld.

Further, even when combined, the catheter and metallic elements described by Wirtzfeld do not together meet the requirements of amended claim 7 with respect to the recited coupling

[8] Office Action, page 3.

module. As amended, claim 7 does not merely require that the coupling module include a metallic element. Instead, amended claim 7 requires that the coupling module be made of metal that defines a lumen between the first and second housings. The metallic elements described by Wirtzfeld are made of metal, but, as discussed above, are internal components of the sensor module. Therefore, it cannot be argued that the metallic elements define a lumen between modules, e.g., between the sensor element and pacemaker, as required by amended claim 7.

None of the other applied references teaches or suggests a coupling module that is fixedly coupled to first and second housings, and is made of metal that defines a lumen between the first and second housings, as required by amended claim 7.

As another example, Wirtzfeld fails to teach or suggest a coupling module that is made of titanium that defines a lumen between first and second housings, as required by claim 17. The Examiner does not appear to have addressed the requirements of claim 17. Wirtzfeld does not teach or suggest that the described metallic elements may be made of titanium.

As another example, Wirtzfeld fails to teach or suggest a coupling module that is hermetically fixed to at least one of first and second housings, as required by claim 12. The Examiner does not appear to have addressed the requirements of claim 12. Wirtzfeld does not discuss hermeticity at all, much less teach or suggest this requirement of claim 12.

As yet another example, Wirtzfeld fails to teach or suggest a first module that includes control electronics and a second module that comprises a battery, as required by claim 20. Again, the Examiner does not appear to have addressed the requirements of claim 20. The only location for control electronics and a battery suggested by Wirtzfeld is within the described pacemaker. Wirtzfeld does not suggest that either may be located in the sensor module. Accordingly, Wirtzfeld fails to teach of suggest a first module that includes control electronics and a second module that comprises a battery.

Wirtzfeld also fails to teach or suggest a third module and a second coupling module, as required by claim 19. Again, the Examiner appears to have completely failed to address the requirements of one of Applicant's claims, which is rejected under section 102, yet clearly not anticipated by the applied reference. Applicant respectfully requests that the Examiner address the requirements of each of Applicant's claims, as required by 37 C.F.R. § 1.104 and the Administrative Procedure Act.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 7, 8, 11, 12 and 14-23 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

**Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected: claims 2 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Wirtzfeld in view of Reischl; claims 4, 9 and 10 under 35 U.S.C. § 103(a) as being unpatentable over Wirtzfeld in view of U.S. Patent No. 6,490,486 to Bradley (Bradley); and claim 13 as being unpatentable under 35 U.S.C. § 103(a) over Wirtzfeld in view of U.S. Patent No. 5,776169 to Schroeppel (Schroeppel). Applicant respectfully traverses these rejections, to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, and provide no teaching that would have suggested the desirability of modification to include such features.

As an initial matter, Applicant notes that none Reischl, Bradley or Schroeppel provides any teaching that would overcome the deficiencies of Wirtzfeld with respect to Applicant's independent claims 1 and 7. For at least this reason the rejections of claims 2, 4, 6, 9, 10 and 13 under section 103 must be withdrawn.

Further, with respect to claim 13, the Examiner argues that it would have been obvious to one of ordinary skill in the art to modify the catheter described by Wirtzfeld to include a bellows hinge as described by Schroeppel for the purpose of enhancing the flexibility of the catheter. This is incorrect. Schroeppel teaches that a bellows section may be added to an otherwise rigid housing for the purpose of providing some flexibility. One of ordinary skill in the art would have understood that the cardiac catheter described by Wirtzfeld, like most cardiac catheters at the time, would have already been very flexible.[9] In other words, it does not appear that adding a bellows as described by Schroeppel would have increased the flexibility of the Wirtzfeld catheter. In any event, the teachings of Schroeppel would not have motivated one of ordinary skill to make such a modification to the Wirtzfeld catheter to increase its flexibility.

[9] See Wirtzfeld: column 3, lines 14-21.

**New Claims:**

Applicant has added a dependent claim 24 and an independent claims 25 to the pending application. The applied references fail to disclose or suggest the features recited by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to include such features. For example, the references fail to disclose or a coupling module that is hermetically fixed to at least one of first and second housings, as recited in new independent claim 25 and discussed above with reference to claim 12. No new matter has been added by the new claims.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 9/26/05

By: _____

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jason D. Kelly
Reg. No.: 54,213